

GUIDE FOR ASSIGNED REVIEWERS' PRELIMINARY COMMENTS ON ACADEMIC CAREER AWARD (K07) APPLICATIONS

PA NUMBER: PA-00-070

Complete details at: <http://grants.nih.gov/grants/guide/pa-files/PA-00-070.html>

NIH Institutes and Centers (ICs) use the Academic Career Award (K07) to support individuals interested in introducing or improving curricula in a particular scientific field as a means of enhancing the educational or research capacity at the grantee's institution.

This Academic Career Award (K07) supports two types of activities:

Development: The K07 provides up to five years of support for more junior candidates who are interested in developing academic and research expertise in a particular field, as a way to increase the overall pool of individuals capable of research or teaching in the identified area. During the period of the award, the candidate will become a successful academician in the chosen area. Teaching, curriculum building, research, and leadership skills are to be learned during the tenure of the award. For junior candidates, a mentor is required.

Leadership: The K07 can also provide from two to five years of support for more senior individuals with acknowledged scientific expertise and leadership skills who are interested in improving the curricula and enhancing the research capacity within an academic institution. It is expected that support under this award will increase the visibility and the overall research support or academic capacity for the given field of research within the academic medical/health and research community.

General Considerations when reviewing K07 applications:

- Candidates for this award must have a clinical or research doctoral degree.
- Candidates for the Development Award must:
 1. Demonstrate the potential to develop into an excellent academician, in the fields of interest to the NIH awarding institute or center
 2. Be able to identify a mentor who is an expert in the research field of interest and has a record of providing the type of supervision required by this award.
 3. Devote at least 75 percent of full-time professional effort to the research and developmental programs required for academic development.
- Candidates for the Leadership Award must:
 1. Have sufficient clinical training, research, or teaching experience in the academic area of interest to the NIH to implement a program of curriculum development within the applicant institution
 2. Must have an academic appointment at a level sufficient to enable her/him to exert an influence on the coordination of research, teaching, and clinical practice in an emerging field
 3. Must be in a position to devote at least 25 but not more than 50 percent effort to the program, a portion of which may include research
- Applications may be submitted, on behalf of candidates, by domestic, non-Federal organizations, public or private, such as medical, dental, or nursing schools or other institutions of higher education.

CRITIQUE

Each major review element within the Academic Career Award application (Candidate, Career Development Plan, Research Plan, Mentor, Environment, and Budget) should be commented on in a separate section of your written critique. For revised applications, also comment briefly on whether the application is improved, the same, or worse. In addition, provide a one-sentence summary of your evaluation at the end of each section. After considering all of the review criteria, briefly summarize the strengths and weaknesses of the application and recommend an overall level of merit in a section titled Summary and Recommendations (see below). Please note that your comments will be used essentially unedited in the final summary statement sent to the candidate.

The following review criteria will be applied:

(Note that different NIH Institutes and Centers may employ different or additional review criteria)

Candidate

- Evidence of excellence in academic, research, and (where appropriate) clinical activities
- Potential to become an outstanding investigator, teacher, resource person, and leader in research, educational and (where appropriate) clinical programs related to the mission of the NIH award component
- Potential to become or to continue as an independent researcher
- Quality and breadth of prior scientific training and experience
- Degree and extent of previous research support and publications considering the academic level of candidate

Career Development Plan

- Quality and feasibility of the candidate's career development plan, including plans after termination of the award
- Quality of the proposed plan to enhance pedagogical and leadership skills
- Quality of the plan to receive training or provide instruction in the responsible conduct of research.

Research Plan

- Quality and feasibility of the research and teaching plan
- Relationship of the research plan to the career development goals and the candidate's previous experience
- Adequacy of plans to include both genders, children, and minorities and their subgroups as appropriate for the scientific goals of the research
- Plans for the recruitment and retention of subjects

Mentor

- For the development academic award, the mentor's prior experience and record in fostering academic growth and productivity
- History of research productivity and peer-reviewed research support
- Adequacy of active and pending support for the proposed research project

Environment

- Commitment of the institution to strengthening research and education activities in the area of interest to the NIH institute or center
- Commitment of the institution to the proposed level of effort related to this award
- Merit of the institution plan to strengthen research and training activities beyond the current status of activities and capacities
- Scope and nature of collaboration among participating schools and Departments
- Adequacy of the research facilities and training opportunities for this award.

SUMMARY AND RECOMMENDATION

In one paragraph, briefly summarize the most important points of the Critique, addressing the strengths and weaknesses of the application in terms of the six review criteria. An application does not need to be strong in all categories to receive a good rating. Each scored application will receive a numerical rating that will reflect your opinion of its merit. The numerical rating is based on a scale from 1.0 for the most meritorious to 5.0 for the least meritorious with increments of 0.1 unit. Reviewers should score the "average" application they customarily review in their Scientific Review Group with a score of 3.0. This practice is designed to have 3.0 be the median.

Protection of Human Subjects from Research Risks: Evaluate the application with reference to the following criteria: risk to subjects, adequacy of protection against risks, potential benefit to the subjects and to others, importance of the knowledge to be gained. (If the applicant fails to address **all** of these elements, notify the SRA immediately to determine if the application should be withdrawn.) If all of the criteria are adequately addressed, and there are no concerns. Write "Acceptable Risks and/or Adequate Protections." A brief explanation is advisable. If one or more criteria are inadequately addressed, write, "Unacceptable Risks and/or Inadequate Protections" and document the actual or potential issues that create the human subjects concern. If the application indicates that the proposed human subjects research is exempt from coverage by the regulations, determine if adequate justification is provided. If the claimed exemption is not justified, indicate "Unacceptable" and explain why you reached this conclusion. Also, if a clinical trial is proposed, evaluate the Data and Safety Monitoring Plan. (If the plan is absent, notify the SRA immediately to determine if the application should be withdrawn.) Indicate if the plan is "Acceptable" or "Unacceptable", and, if unacceptable, explain why it is unacceptable.

Inclusion of Women Plan:

Inclusion of Minorities Plan:

Inclusion of Children Plan:

Public Law 103-43 requires that women and minorities must be included in all NIH-supported clinical research projects involving human subjects unless a clear and compelling rationale establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. NIH requires that children (individuals under the age of 21) of all ages be involved in all human subjects research supported by the NIH unless there are scientific or ethical reasons for excluding them. Each project involving human subjects must be assigned a code using the categories "1" to "5" below. Category 5 for minority representation in the

project means that only foreign subjects are in the study population (no U.S. subjects). If the study uses both then use codes 1 thru 4. Examine whether the minority and gender characteristics of the sample are scientifically acceptable, consistent with the aims of the project, and comply with NIH policy. For each category, determine if the proposed subject recruitment targets are "A" (acceptable) or "U" (unacceptable). If you rate the sample as "U", consider this feature a weakness in the research design and reflect it in the overall score. Explain the reasons for the recommended codes; this is particularly critical for any item coded "U".

Category	Gender (G)	Minority (M)	Children (C)
1	Both Genders	Minority & non-minority	Children & adults
2	Only Women	Only minority	Only children
3	Only Men	Only non-minority	No children included
4	Gender unknown	Minority representation unknown	Representation of children unknown
5	Only Foreign Subjects		

NOTE: To the degree that acceptability or unacceptability affects the investigator's approach to the proposed research, such comments should appear under "Approach" in the five major review criteria above, and should be factored into the score as appropriate.

Vertebrate Animals: Express any comments or concerns about the appropriateness of the responses to the five required points, especially whether the procedures will be limited to those that are unavoidable in the conduct of scientifically sound research.

Biohazards: Note any materials or procedures that are potentially hazardous to research personnel and indicate whether the protection proposed will be adequate.

OTHER CONSIDERATIONS: These comments are useful to NIH but should not influence your overall score.

Foreign Training: In a separate section, describe the scientific advantages of the proposed training in a foreign country and compare it to relevant training opportunities available in this country. Comment on any special talents, resources, populations, or environmental conditions that are not readily available in the United States or that augment existing resources. This consideration should not be factored into your overall recommendation and rating.

Administrative Note: (e.g., There is potential overcommitment and/or scientific overlap with other existing grants and/or pending applications.)

Data Sharing Plan: Applications requesting more than \$500,000 direct costs in any year of the proposed research are expected to include a data sharing plan in their application. Certain Program Announcements may request a data sharing plan for all

applications regardless of the amount of direct costs. Assess the reasonableness of the data sharing plan or the rationale for not sharing research data.

Model Organism Sharing Plan: The NIH policy on sharing of model organisms for biomedical research was announced in the May 7, 2004 issue of the NIH Guide (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>). Starting with the October 1, 2004 receipt date, all new and competing-renewal NIH grant applications that plan to produce model organisms will be expected to include a sharing plan. Unlike the NIH Data Sharing Policy, the submission of a model organism sharing plan is NOT subject to a cost threshold of \$500,000 or more in direct costs in any one year, and is expected to be included in all applications where the development of model organisms is anticipated.

Budget: Evaluate the justification of budget requests in relation to career development goals and research aims and plans.

Further information about NIH research training and career development opportunities can be found at <http://grants.nih.gov/training>

Updated: 05/12/2006